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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,787	01/26/2001	Christophe Francois Guy Gilbert	031855.0091	4454

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	11

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/769,787	Applicant(s) GILBERT ET AL.
	Examiner Padmavathi v Baskar	Art Unit 1645

-- The MAILING DATE of this communication app ars on th cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/10
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I Claims 7-8 and13 drawn to DNA, host cell and a vaccine composition. classified in class 536, subclass 23.7. Further election of invention required.

II Claims 1-6 and10-12 drawn to polypeptide, classified in class 424, subclass 190.1. Further election of invention required.

III Claims 15-16 drawn to an antibody classified in class 530, subclass 388.6 Further election of invention required.

IV Claim 9 drawn to a method for inducing immune response using polypeptide classified in class 424, subclass 165.1 Further election of invention required.

V Claim 20 drawn to a method of use for the treatment or prophylaxis of S.pneumoniae infection using protein or polypeptide classified in class 424, subclass 184.1 Further election of invention required.

VI Claim 19 drawn to a method of determining whether a protein is anti-microbial target in vivo or in vitro classified in class 424, subclass 93.1 Further election of invention required.

VII Claim 18 drawn to a method of detecting S.pneumoniae infection using nucleic acid, SEQ.ID.NO: 1 classified in class 435, subclass 6. Further election of invention required.

VIII Claim 14 drawn to a method of detecting S.pneumoniae infection using protein antigen, SEQ.ID.NO: 2 classified in class 435, subclass 7.22. Further election of invention required.

IX Claims 17 drawn to a method of detecting S.pneumoniae infection using antibody classified in class 435, subclass 7.22. Further election of invention required.

2. The inventions are distinct, each from the other because of the following reasons:

Group I is directed to DNA, which consists of nucleic acids, Groups II is directed polypeptides which are made of amino acids, Invention III is drawn to an antibody and is distinct from Inventions I-II since it has an inherent affinity, avidity, and specificity that a DNA or a simple protein is not capable of expressing. Thus these products, (i.e., Group I/II/III) are different to each other structurally, biochemically and functionally.

Groups IV-IX are different methods utilizing different products with different structure and biological properties. Inventions VII-IX are drawn to different methods detecting of S.pneumoniae infection utilizing different biological reagents such as nucleic acids, proteins, and antibodies respectively. Inventions IV-VI are drawn to different methods such as inducing an immune response, for the prophylactic treatment or of S.pneumoniae infection, and for identifying a protein which is a candidate anti-microbial target utilizing different products namely nucleic acids, proteins and antibodies respectively. Thus Inventions IV, V, VI, VII, VIII and IX are different methods using different biological reagents, different method steps which result in different outcome.

3. Invention II is related to inventions V, and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in immunoaffinity chromatography methods for purifying antibodies and need not be used in the inventions V, and VIII

4. Invention I is related to inventions IV and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used to make probes for using it in vitro hybridization and need not be used in the inventions IV and VII

5. Invention III is related to inventions VI and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used in immunoaffinity chromatography for purifying antigens and need not be used in the inventions VI and IX

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

DISTINCT INVENTIONS

7. Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patentably distinct inventions for the following reasons.

Groups I- IX contain claims (1-20) reciting plurality of disclosed patentably distinct invention with distinct nucleic acid or amino acid sequences as represented in Tables 1-4. Applicant is required under 35 U.S.C. 121 and advised to elect a single disclosed sequence from these tables and identify the sequence with a SEQ.ID.NO with specific amino acid or nucleic acid.

8. During a telephone conversation with Laurence Posorske on 7/9/02 a provisional election was made without traverse to prosecute the invention of V, claim 20 with respect to amino acid sequence from Table 3: ID 211-4127.2 (SEQ.ID.NO: 162) Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-19 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant is advised to amend the claims to recite SEQ.ID.NO: 162.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

10. Applicant's claim for domestic priority under 35 U.S.C. 119(e) for provisional application 60/125,164, 3/19/1999 is acknowledged. This application is a continuation of PCT/GB99/02452, 7/27/1999, which claims priority to Foreign Application ~~Germany~~ GB 9816337.1, 7/27/1998. Acknowledgment is made of applicant's claim 20 for foreign priority based on an application filed in ~~Germany~~ GB on 7/27/1998. It is noted, however, that applicant has not filed a certified copy of the ~~Germany~~ GB 9816337.1 application as required by 35 U.S.C. 119(b). A certified and translated copy of ~~Germany~~ GB 9816337 application is required to grant priority for claim 20 as of 7/27/1998 in this application as the Examiner is not versed in German language.

Specification Informalities

11. Applicant should follow the direction or order or arrangement in framing the specification as provided in 37 CFR 1.77(b) since this is a utility application filed in USA. The specification

should include all the sections in order. For example: There is no brief description of the drawing as set forth in 37 C.F.R.1.74.

Claims should begin with "I claim" or "We claim" or "What is claimed is".

Applicants have submitted a paper and electronic copy of Sequence listing which contains 388 sequences and are identified as SEQ.ID.NOS: 1-388 as part of the originally filed subject matter. The specification does not contain an incorporation of these SEQ.ID.NOS by reference. However, the specification contains Tables, 1-4. Applicant(s) are required to insert SEQ.ID.NOS in the specification. See 37 CFR 1.77(b)(4).

Information Disclosure Statement

12. Information Disclosure Statements filed on 3/22/01 (Paper # 3) and 8/15/02 (Paper # 10) are acknowledged and a signed copy of each is attached to this Office action.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

14. Claim 20 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101("use" is not one of the statutory classes of invention). See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

16. Claim 20 provides for the use in the treatment or prophylaxis of S.pneumoniae infection (i.e., an agent capable of antagonizing, inhibiting or otherwise interfering) but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

17. Claim 20 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the claims do not recite positive active steps so that the claims will set out and circumscribe particular area with reasonable degree of precision and particularity and make clear what subject matter the claims encompass, as well as make clear the subject matter from which others would be precluded. See Ex parte Erlich, 3 USPQ2d 1011 (BPAI, 1987).

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is indefinite as it is drawn to a polypeptide, which is identified by a Table. The inclusion of additional structural parameters, such as amino acid sequence of the polypeptide (for example; SEQ.ID.NO), would enable more definitive identification of the claimed polypeptide without ambiguity.

Applicant is advised to recite the SEQ.ID.NO: 162 while amending the claim.

Claim 20 is rejected as being vague for the recitation of "capable of ". As written it is difficult to determine the metes and bound of "capable of " Does this agent inhibit or cure or treat or prevent the infection?

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kunsch et al U.S.Patent: 6,420,135 (102 e date 10/31/1996).

Kunsch et al disclose an agent, polynucleotide from position 8112-7024 (SEQ.ID.O: 127) encoding a polypeptide comprising 373 amino acids as set forth in SEQ.ID.NO: 162 in the present application.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar
~~9/10/02~~
9/19/02

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600